Moreover, both Project Wheat and other Brown & Williamson research demonstrate that the company knew that "Inner Need" level corresponded to the smoker's use of cigarettes for pharmacological effects. Project Wheat researchers concluded that future studies to design cigarettes with acceptable nicotine levels should classify smokers along a single dimension of inner need that might correspond to "pharmacological addiction":

> [I]t would be preferable to position respondents along the single dimension of Inner Need. . . . the suggestion is very much in line with that made by Russell . . . who . . . concluded that *it might prove more useful to classify smokers according to their position on a single dimension of pharmacological addiction* rather than in terms of their profiles on the six types of smoking.[930]

Brown & Williamson's assertion that stress relief, aided concentration, and weight control are not among the principal pharmacological effects of nicotine is not credible. In fact, as early as 1962, Project HIPPO concluded that nicotine's most significant pharmacological benefits were its ability to relieve stress and to control weight gain.[931]

Contrary to Brown & Williamson's argument, Project Wheat found a correlation between inner need level and preferred nicotine delivery.[932] Thus, the Project Wheat researchers concluded that inner need correlated with preferred nicotine delivery and agreed with Russell that inner need is related to pharmacological addiction.

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[930] Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 49 (citation omitted) (emphasis added). *See* AR (Vol. 20 Ref. 204-2).

[931] Haselbach CH, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 2. *See* AR (Vol. 14 Ref. 163-1).

[932] Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 47-48 ("High Need clusters tend to prefer relatively high nicotine cigarettes, and . . . their optimum nicotine delivery is certainly higher than is that of the Low Need clusters.") *See* AR (Vol. 20 Ref. 204-2).

3. A comment from Brown & Williamson claims that the company has never marketed a product that used "elasticity" to enable smokers to compensate for lowered nicotine yields. The company concedes that internal documents show that "BATCO explored the possibility of using its knowledge of compensation in the development of low 'tar' products" but claims that these were only theoretical discussions.[933]

FDA relied, in part, on the industry's product development research on increasing nicotine as evidence that the industry understands that tobacco satisfaction is a function of the pharmacological effects of nicotine and of the industry's attempts, successful or not, to ensure that tobacco users receive sufficient nicotine to achieve those effects. FDA did not rely on this research as evidence that the researched products were marketed.

In fact, however, there is good reason to believe that Brown & Williamson, as well as other tobacco companies, have incorporated "elasticity" into their marketed products. For example, Brown & Williamson's Barclay cigarettes were promoted as ultra-low cigarettes, with advertised deliveries of 1 mg tar and .02 mg nicotine, as measured by the FTC method. *Federal Trade Commission v. Brown & Williamson*, 778 F.2d 35, 37 (D.C. Cir. 1985). Philip Morris and RJR complained to the FTC that Barclay's channel-ventilated filter system allowed the cigarette to produce low tar and nicotine yields when measured by the FTC (smoking machine) method, but to actually deliver far more tar and nicotine to the smoker. According to the complaint, the FTC smoking machine is able to "smoke" the cigarette without obstructing Barclay's unique ventilation system, but "when the cigarette is smoked between human lips its air ventilation system is inevitably

[933] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 42. *See* AR (Vol. 529 Ref. 104).

obstructed and the cigarette delivers disproportionately more tar and nicotine than other comparably rated cigarettes." *Id.* at 37.

The FTC brought an enforcement proceeding to enjoin Brown & Williamson from using the FTC tar and nicotine figures in Barclay advertisements. *Federal Trade Commission v. Brown & Williamson*, 580 F. Supp. 981 (D.D.C. 1983), *aff'd in part, rev'd in part*, 778 F.2d 35 (D.C. Cir. 1985). The district court found, and the Court of Appeals agreed, that use of the FTC tar and nicotine figures for Barclay was false and misleading, because—primarily as a result of its channel-ventilated filter system—Barclay delivers significantly more tar and nicotine to the smoker than indicated by the FTC yields. 580 F. Supp. at 989; 778 F.2d at 41-42. Thus, Barclay represents a clear example of the use of filter technology to provide elasticity, i.e., to enable the smoker to extract more nicotine from the smoke than the advertised yield.

Brown & Williamson argues that Barclay is not an example of a product designed to provide elasticity, and that there is no evidence to support FDA's claim that the channel-ventilated filter boosts nicotine delivery. FDA disagrees. The district court opinion in *Federal Trade Commission v. Brown & Williamson* demonstrates that Barclay cigarettes deliver substantially more nicotine than their advertised yields and that this increase in nicotine delivery over the machine-tested yield is due to compromising the channel-ventilated filter during human smoking. The district court cited a study submitted by Brown & Williamson, which found that "smokers who smoked Barclay received approximately 1-1/2 to 2 times as much nicotine into their systems as smokers of the other cigarettes [with comparable FTC ratings] tested." 580 F. Supp. at 988. The court also

found that the increase in nicotine and tar deliveries was due to compromising the ventilation system under actual smoking conditions. 580 F. Supp. at 989.

The conclusion that Barclay was designed to provide elasticity is also supported by evidence that Barclay was reported to contain significantly more nicotine than comparable cigarettes. As described above in section II.C.4., an independent study conducted in 1982 showed that Barclay had both the highest nicotine concentration and the most total nicotine in the rod of all the cigarette brands tested, including regular strength (high tar/high nicotine) cigarettes.[934] Compared to the other cigarettes with comparable FTC nicotine ratings (≤0.2 mg nicotine, as published in 1981 FTC Report) that were tested, Barclay contained a tobacco blend with a 50% to 95% higher nicotine concentration, and 20% to 85% more total nicotine. Thus, while Barclay had among the lowest FTC yields, it delivered a significantly higher level of nicotine during human smoking because (1) it contained more nicotine than any comparable cigarette, and (2) the nature of the filter permitted smokers to defeat the ventilation system and obtain substantially more nicotine than the advertised yield (1-1/2 to 2 times the nicotine of comparable cigarettes, according to Brown & Williamson's own study).

iv. Other Comments.

1. Comments from the tobacco industry argue that the tobacco company studies cited by FDA do not support the finding that smokers compensate. One comment argues that Brown & Williamson and BATCO researchers did not acknowledge that

[934] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 173 (Jun. 23, 1994) (data from Neal Benowitz). *See* AR (Vol. 709 Ref. 3).

smokers compensate to obtain a dose of nicotine that satisfies a physiological need. This comment does concede, however, that it is "hardly news" that "the phenomenon of compensation was internally 'recognized' or 'acknowledged' by tobacco manufacturers."[935] This comment also argues that reductions in tar and nicotine yields have resulted in reductions of the amount of nicotine obtained by smokers. On the other hand, a comment from a public health organization provided additional examples of industry statements and research on compensation.[936]

FDA has reviewed the studies relied on in this section of the Jurisdictional Analysis and concludes that they provide a wealth of evidence that the tobacco industry understands that smokers compensate to obtain a desired dose of nicotine. The contention that these studies fail to demonstrate compensation cannot be supported. For example, BATCO researchers stated in 1984 that "it is accepted that nicotine is both the driving force and the signal (as impact) for compensation in human smoking behavior."[937]

A large number of additional industry studies cited by FDA found that compensation occurred to one degree or another. *See* Jurisdictional Analysis, 60 FR 41659–41666. Throughout these studies and conference reports, tobacco company officials consistently recognize that compensation behaviors occur to adjust nicotine dose. The public health organization comment provided several additional examples of tobacco industry acknowledgment that compensation occurs because smokers are attempting to

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[935] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 40. *See* AR (Vol. 529 Ref. 104).

[936] American Society of Addiction Medicine, Comment (Dec. 29, 1995), Table 6. *See* AR (Vol. 528 Ref. 97).

[937] Minutes of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at 56. *See* AR (Vol. 25 Ref. 325-1).

maintain their customary nicotine dose. For example, a 1981 monograph on nicotine published by the Tobacco Advisory Council (an industry organization of which BATCO was a member) reviewed the evidence on compensation and concluded that while regulation of nicotine intake is not consistently seen in every study:

> Human subjects appear to modify their smoking behaviour to maintain the total dosage of nicotine when they smoke cigarettes of varying nicotine content. . . . Studies of nicotine antagonists indicate that smokers seek an effective brain level of nicotine when modifying their smoking behaviour.[938]

Accordingly, the industry's research amply supports FDA's conclusion that the tobacco industry knows that smokers use cigarettes to "compensate"—to obtain desired doses of nicotine.

2. One comment from a tobacco manufacturer argues that "much" of the nicotine-related research did not result in alterations to marketed products, and a comment from another cigarette manufacturer argues that its product development research did not result in the addition of "extraneous nicotine."

The claim that some of the industry's research did not result in changes to commercial-marketed products does not alter the relevance of the industry's research to establishing manufacturers' awareness of the pharmacological effects of nicotine. As noted above, the knowledge produced by the research is evidence of intended use. Moreover, there is a great deal of evidence that the knowledge was acted upon. Even the industry comments do not claim that none of the research was acted upon. For example, the brands of cigarettes advertised as lowest in tar and nicotine have the highest

[938] Cohen AJ, Roe JC (Tobacco Advisory Council), *Monograph on the 'Pharmacology and Toxicology of Nicotine'* (1981), at 38 (citation omitted). *See* AR (Vol. 34 Ref. 583).

concentrations of nicotine on the market, reflecting industry to ensure that nicotine levels in low-yield products do not fall below minimum levels that consumers will accept. *See* section II.C.4.a., above.

Finally, the argument that none of the product development research resulted in the addition of "extraneous nicotine" to commercial cigarettes is irrelevant to establishing intended use. Whether or not this statement is true, the research, in and of itself, establishes the knowledge of tobacco manufacturers that nicotine delivery is essential to the success of their products. In addition, the evidence shows that nicotine has actually been manipulated in commercial cigarettes, demonstrating that tobacco manufacturers have not merely researched but have taken affirmative steps to ensure the delivery of an adequate dose of nicotine. *See* Jurisdictional Analysis, 60 FR 41693–41733. It is the fact that the industry has manipulated nicotine delivery, rather than the manner in which it is accomplished, that is relevant to establishing the intended use of these products.

c. Comments on Nicotine Manipulation and Control

i. Comments on the Use of High-Nicotine Blends in Low-Yield Cigarettes.

1. The cigarette manufacturers contend that the use of high-nicotine blends in low-tar cigarettes does not affect the nicotine delivery of these cigarettes. According to the manufacturers, the increase in nicotine from the use of high-yield blends is more than offset by other design features, such as a reduction in the total mass of tobacco in the cigarette and increased filtration and ventilation.

The Agency disagrees. It is beyond reasonable dispute that the use of high-nicotine blends does affect nicotine deliveries. Indeed, the joint comment of the manufacturers acknowledge this point. The comment concedes that "nicotine content of

the leaf" is one of the "*factors that determine the nicotine yield in the cigarette smoke.*"[939] Of the four factors that the comment lists as determining nicotine yield, two of the factors —"the blend itself" and "the percentage of processed tobaccos"[940]—relate directly to the concentration of nicotine in the cigarette rod. Similarly, Alexander Spears, the vice chairman and chief operating officer of Lorillard, has acknowledged that among other factors, "*the nicotine yield of a cigarette is determined by the nicotine content of the tobacco.*"[941]

Although it may be true that other design features of low-tar cigarettes reduce nicotine deliveries, the use of high-nicotine blends is designed to *offset* those reductions. Thus, high-nicotine blends result in higher nicotine deliveries than would be provided by a low-tar cigarette that did not use such blends.

Moreover, the nicotine yields measured on an FTC smoking machine do not accurately predict the amount of nicotine that will be inhaled and absorbed by smokers because smokers of low-yield products frequently compensate for the low nicotine deliveries by inhaling more deeply or puffing more frequently. *See* Jurisdictional Analysis, 60 FR 41573–41574. The use of higher nicotine blends in low-yield cigarettes increases the total amount of nicotine that is available to be extracted by smokers.

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[939] Joint Comment of Cigarette Manufacturers, Comment, (Jan. 2, 1996), Vol. IV, at 69 (emphasis added). *See* AR (Vol. 535 Ref. 96).

[940] *Id.* at 70.

[941] Spears AW (Lorillard Tobacco Co.), *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide*, presented at the 1975 Symposium-Nicotine and Carbon Dioxide (Nov. 17-18, 1975), in *Symposium Proceedings-1*, 12-18, at 13 (emphasis added). *See* AR (Vol. 27 Ref. 395a).

2. Brown & Williamson's comments concede that it used Y-1, a high-nicotine tobacco, in marketed cigarettes. The comments assert, however, that Y-1 "was never used by B&W for the purpose of altering the ratio of nicotine to tar in the smoke of any commercialized brands."[942] What is beyond dispute, however, is the original purpose of the creation of Y-1. As described in section II.C.3.c.iii., Brown & Williamson developed Y-1 as a "blending tool" so that it could maintain nicotine levels while tar levels dropped. Y-1 is thus a central example of product research and development to enhance nicotine deliveries.

ii. Comments on Nicotine Deliveries and Nicotine-to-Tar Ratios.

1. The cigarette industry asserts in its comments that the reduction in the nicotine delivery of cigarettes over the last 40 years demonstrates that the industry has not sought to control or manipulate nicotine. According to the industry, nicotine deliveries have dropped by 60% over the last 40 years. The industry maintains that the fact that cigarette manufacturers have reduced nicotine deliveries shows that the manufacturers do not control or manipulate nicotine deliveries to provide a pharmacologically active dose of nicotine.

The Agency agrees that nicotine deliveries as measured by smoking machines have declined over the last 40 years. This comparison is misleading, however. The recent trends show that nicotine deliveries have stopped declining and are, in fact, *increasing* — especially in low-tar cigarettes. From 1982 to 1991, the nicotine deliveries in the lowest-tar category of cigarettes increased approximately 15%. *See* Jurisdictional Analysis, 60

[942] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 32. *See* AR (Vol. 529 Ref. 104).

FR 41731. Although the industry maintains that "[n]icotine levels follow the tar level" in "essentially perfect correlation"[943] and that this correlation shows that the industry does not manipulate nicotine,[944] nicotine deliveries did not follow tar deliveries during this period. Rather, while nicotine deliveries were increasing from 1982 to 1991, tar deliveries declined or remained essentially flat.[945]

The recent trend of increasing nicotine deliveries in low-tar cigarettes supports the Agency's finding that the cigarette manufacturers have controlled and manipulated nicotine to maintain a pharmacologically active dose. The trend is evidence that as tar deliveries dropped to low and ultra-low levels in the late 1970's and the 1980's, the manufacturers took steps to maintain a pharmacologically active nicotine dose by enhancing nicotine deliveries.

The overall trend in nicotine deliveries is also fully consistent with—and indeed corroborates—the Agency's position. Forty years ago, cigarettes delivered over 2.5 mg of nicotine per cigarette.[946] According to tobacco industry documents, however, nicotine deliveries as low as 0.5 to 0.8 mg per cigarette "provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker."[947] Thus, nicotine

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[943] *Regulation of Tobacco Products (Part 1), Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 378 (Mar. 25, 1994) (statement of Alexander Spears). *See* AR (Vol. 707 Ref. 1).

[944] *Id.*

[945] From 1982 to 1991, nicotine deliveries increased in ultra-low-tar, low-tar, and high-tar cigarettes. Tar deliveries, however, decreased in the high-tar and low-tar categories and increased only marginally (approximately 3%) in the ultra-low-tar category. *See* Jurisdictional Analysis, 60 FR 41728-41731.

[946] Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. III, "Sales Weighted Average 'Tar' and Smoke Nicotine"Graph. *See* AR (Vol. 535 Ref. 96).

[947] Senkus M (R. J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 12 (emphasis added). *See* AR (Vol. 700 Ref. 593).